

records. If the affected person fails to intervene to defend the exempt status of the records and to itemize and index the disputed records, the Food and Drug Administration will take this failure into consideration in deciding whether that person has waived such exemption so as to require the Food and Drug Administration to promptly make the records available for public disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994]

Subpart D—Exemptions

§ 20.60 Applicability of exemptions.

(a) The exemptions established in this subpart shall apply to all Food and Drug Administration records, except as provided in subpart E of this part. Accordingly, a record that is ordinarily available for public disclosure in accordance with the provisions in subpart F of this part or of another regulation cross-referenced in § 20.100(c) is not available for such disclosure to the extent that it falls within an exemption contained in this subpart, except as provided by the limitations on exemptions specified in subpart E of this part. For example, correspondence that is ordinarily disclosable under § 20.103 is not disclosable to the extent that it contains trade secrets exempt from disclosure under § 20.61 and is not subject to discretionary release under § 20.82.

(b) Where application of one or more exemptions results in a record being disclosable in part and nondisclosable in part, the rule established in § 20.22 shall apply.

§ 20.61 Trade secrets and commercial or financial information which is privileged or confidential.

(a) A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

(b) Commercial or financial information that is privileged or confidential means valuable data or information

which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

(c) Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

(d) A person who submits records to the Government may designate part or all of the information in such records as exempt from disclosure under exemption 4 of the Freedom of Information Act. The person may make this designation either at the time the records are submitted to the Government or within a reasonable time thereafter. The designation must be in writing. Where a legend is required by a request for proposals or request for quotations, pursuant to 48 CFR 352.215-12, then that legend is necessary for this purpose. Any such designation will expire 10 years after the records were submitted to the Government.

(e) The procedures in this paragraph apply to records on which the submitter has designated information as provided in paragraph (d) of this section. These procedures also apply to records that were submitted to the Food and Drug Administration when the agency has substantial reason to believe that information in the records could reasonably be considered exempt under exemption 4 of the Freedom of Information Act. Certain exceptions to these procedures are set forth in paragraph (f) of this section.

(1) When the Food and Drug Administration receives a request for such records and determines that disclosure may be required, the Food and Drug Administration will make reasonable efforts to notify the submitter about these facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If the Food and Drug Administration must notify a large number of submitters, notification may be done by posting or publishing a notice in a place